REMARKS

Claims 20-41 currently appear in this application. Claims 25-38, process claims, are withdrawn from further consideration. The Office Action of Mary 24, 2007, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Election/Restriction

It is noted that product claims 20-24 and 39 have been examined and that process claims 25-38 have been withdrawn from consideration. The present amendment does not cancel the withdrawn claims in the event that the product claims are deemed to be patentable the process claims will be considered for rejoinder.

Art Rejections

Claims 20-24 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman et al. WO 98/14209 in view of Boccia et al., *Eur. J. Pediatr.* (2001) **160** 385-391 and in view of Carroll et al., U.S. 5,599,539. This rejection is respectfully traversed.

It is respectfully submitted that it is widely known within the research community that Coleman has claimed many effects of IgY (avian antibody) that have not been scientifically substantiated. Coleman claims, *inter alia*, that antibodies can be absorbed from the intestines and reach peripheral organs such as the mammary gland of a cow, and locally prevent infections in the mammary gland. Scientifically, there is no evidence that active antibodies can be absorbed from the intestines of either a cow or a human. If this were possible, this would then cause an antibody response, and such a response has so far not yet been proven.

Moreover, Coleman was convicted by the US District Court for the Southern District of Ohio, which conviction was affirmed by the Court of Appeals for the Sixth Circuit (*United States of America v. Mitchell v. Kaminski, Marilyn a,. Coleman, and Ovimmune, Inc*. August 31, 2007, of fifteen misdemeanor counts of introduction into interstate commerce of unapproved new drugs, introducing into interstate commerce of misbranded drugs, failure to register a drug manufacturing facility, misbranding drugs, and adulterating drugs, under the Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq*. A copy of this decision is attached hereto.

While a disclosure that is inoperative is enabling for what it discloses, in this case it appears that there is no substantiation for the allegation that the avian antibodies can actually be used to treat enteric infections in immunocompromised patients. As the CCPA stated in *In re Sasse*, 207 USPQ 107,111 (C.C.P.A. 1980), "When the PTO cited a disclosure which expressly anticipated the present invention... the burden was shifted to the applicant. He had to rebut the presumption of the operability of [the prior art patent] by a preponderance of the evidence." The Federal Circuit, in *Amgen, Inc. v. Hoechst Marion Roussel Inc.* 65 USPQ 2d 1385 (Fed. Cir. 2003), stated "the applicant can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled" 1416.

In the present case, it is clear from the case against Coleman and her co-inventor Kaminski, that no one skilled in the art would have relied on the Coleman patent for teaching that avian antibodies can actually be used to treat enteric infections in immunocompromised patients. While Coleman may have disclosed that passive immunization has been shown to protect individuals, there is no evidence presented by Coleman that this passive immunization has actually been effective. In fact, in citing "Several recent studies", no citations have been given. One skilled in the art reading the

allegations against Coleman and Kaminski would be reluctant to give any credence to their patent application.

Coleman is not a valid reference. Boccia merely teaches teat necrotizing enterocolitis is one of the most serious gastrointestinal diseases among newborns, that it mainly affects infants in intensive care units, and that *E. cloacae* is an important causative agent for this disease. Carroll teaches that avian clostridial antitoxin, not avian antibodies, can be mixed with infant formula for ease of administration to infants. However, the combination of Boccia and Carroll does not teach or suggest to one skilled in the art an avian IgY originating from an egg of a bird hyperimjunized with *Enterobacter cloacae*.

Rejections under 35 U.S.C. 112

Claims 24 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

Claims 24 and 39 have been amended to delete the limitations for which there is no antecedent basis. New claims 40 and 41 have been submitted in order to include these limitations.

Claim Objections

Claim 20 is objected to because it is proper for the scientific names of organisms, such as *Enterobacter cloacae*, to be italicized.

Accordingly, claim 20 has been corrected.

Specification

The specification and abstract are objected to because scientific names of organisms are not italicized.

Accordingly, the specification ahs been amended and a new abstract submitted in order to correct these informalities.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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